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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 729,478	12 04 2000	Peter Kushner	407T-896330US	7340

22798 7590 12 13 2001

LAW OFFICES OF JONATHAN ALAN QUINE
P O BOX 458
ALAMEDA, CA 94501

EXAMINER

KEMMERER, ELIZABETH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 12/13 2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/729,478

Applicant(s)

Kushner et al.

Examiner

Elizabeth C. Kemmerer

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4 Dec 2000
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D.11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-26 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of Right to Appeal (PTO 1449) Paper Version
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO 1448)
- 17) ☐ Information Disclosure Statement(s) (PTO 1449) Paper Version
- 18) ☐ Interview Summary (PTO 1449) Paper Version
- 19) ☐ Notice of Informal Patent Application (PTO 1447)
- 20) ☐ Other

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim(s) 1-11, drawn to a method for screening a test compound for the ability to activate transcription through an indirect estrogen response, classified in class 436, subclass 501, for example.
- II. Claim(s) 12, drawn to an estrogen agonist, classification dependent upon structure of agonist.
- III. Claim(s) 13-16, drawn to a method for screening a test compound for the ability to inhibit transcription through an indirect estrogen response, classified in class 435, subclass 7.1, for example.
- IV. Claim(s) 17, drawn to a compound that inhibits transcription through an indirect estrogen response, classification dependent upon structure of the compound.
- V. Claim(s) 18-22, drawn to a method for screening a test environmental compound for estrogenic activity, classified in class 435, subclass 7.2, for example.
- VI. Claim(s) 23-26, drawn to a method of inhibiting agonistic activity of an antiestrogen

The inventions are distinct, each from the other because of the following reasons:

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Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups II and IV are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the agonist of Group II has the opposite activity of the inhibitor of Group IV.

Similarly, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I, III, V and VI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires measurement of transcription activation, which is not required by any of the other groups. Invention III requires measurement of nucleic acid expression, which is not required by any of the other groups. Invention III requires measurement of transcription inhibition and use of a compound known to mediate an indirect estrogen response, which is not required by any of the other groups. Invention V requires screening of environmental compounds, which is not required by any of the other groups. Finally,

Therefore, a search and examination of all three methods in one patent application would result in an undue burden, since the searches for the three methods are not co-extensive, the classification is different, and the subject matter is divergent.

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Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made synthetically.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made synthetically.

Each of the following pairs of inventions are unrelated: II/V; II/VI; IV/V; am IV/VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. The method in each pair does not require the product of each pair.

Rejection is based on the prior art of record. The inventions are not related to the prior art status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673. The examiner can normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ECK

December 12, 2001



I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Assistant Commissioner for Patents.
Attn: Box Missing Parts.
Washington, D.C. 20231. on March 14, 2001
LAW OFFICES OF JONATHAN ALAN QUINE

By Richard A. Pask
Richard Pask

Attorney Docket No. 407T-896330US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Peter J. Kushner et al.

Application No.: 09/729,478

Filed: December 4, 2000

For: **METHODS FOR SCREENING
COMPOUNDS FOR ESTROGENIC
ACTIVITY**

Examiner:

Art Unit:

TRANSMITTAL LETTER - RESPONSE
TO NOTICE OF MISSING PARTS

Attn: Box Missing Parts
Assistant Commissioner for Patents
Washington, D.C. 20231

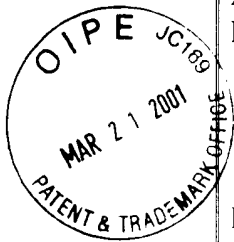
Sir:

Pursuant to the "Notice to File Missing Parts of Application - Filing Date Granted" dated December 20, 2000, enclosed are the following to be made of record in the above-identified application:

- 1) Copy of Executed Declaration from prior application
- 2) Change in correspondence address
- 3) Copy of Notice of Missing Parts

cc transmittal sheet

- 6) Transmittal Sheet
- 7) Receipt indication postcard



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Please charge Deposit Account No. 50-0893 for the following fees:

Large entity:	(a)	Missing Parts Surcharge	\$ 130.00
	(b)	One-month Extension of Time Fee	\$ 110.00
TOTAL FEES TO BE CHARGED			<u>\$240.00</u>

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 50-0893. This Transmittal Letter is submitted in duplicate.

Respectfully submitted,

Tom Hunter, J.D., Ph.D.
Reg. No. 38,498

LAW OFFICES OF JONATHAN ALAN QUINE
P.O. BOX 458
Alameda, CA 94501
(510) 337-7871
Fax (510) 337-7877